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**ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS**

**46<sup>th</sup> Meeting of ACAF on 5 June 2009**

**Information Paper**

**EC DEVELOPMENTS**

**Secretariat: May 2009**

## EC DEVELOPMENTS

1. This paper outlines the main developments in relation to EC legislation and related matters since the ACAF meeting held on 4 March 2009.

### **Official feed and food controls - Regulation (EC) No 882/2004**

#### Implementing rules for import controls for 'high-risk' feed and food of non-animal origin

2. The draft Commission Regulation on these implementing rules received a favourable opinion from the Standing Committee on the Food Chain and Animal Health (SCoFCAH) at its meeting on 27 March 2009. The text will now be subject to European Parliament scrutiny prior to formal adoption by the Commission. It is anticipated that the date of application will be 1 January 2010. In giving its opinion the Standing Committee recognised that decisions about which products should be subject to the provisions in the Regulation must be evidence-based and must be guided by established criteria. Therefore, the Commission gave an undertaking to work with Member States to develop guidelines on this and to review the current list of products in the Regulation before the application date. Stakeholders will be informed of developments via the Rapidly Developing Policy page on the FSA's website at:

<http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/>

3. The Agency is currently considering measures needed to give effect to the Commission Regulation at national level and will be consulting with stakeholders in due course.

### **Undesirable Substances**

4. A public consultation on draft Regulations to implement Commission Directive 2009/8/EC of 10 February 2009 setting carry-over levels for coccidiostats into feed for non-target species commenced on 23 March and will run until 15 June 2009. The levels are set in the form of a new category of undesirable substances in the Annex to Directive 2002/32 on undesirable substances, and is without prejudice to their authorisation as feed additives under EC Regulation 1831/2003 on feed additives. The levels are risk-based, and have been set following an assessment by the European Food Safety Authority of the likely risks to animal and human health.
5. It is hoped that public consultation on another Commission measure, EC Regulation 152/2009 of 27 January 2009 laying down methods of sampling and analysis for feed will commence shortly. The Regulation

applies directly in all Member States and largely consolidates existing sampling and analysis procedures, but significant changes to UK legislation will be required to provide for its enforcement and to remove existing provisions which may conflict with it. It is thought that this may entail some amendments to the Agriculture Act 1970, under which secondary feedingstuffs legislation is made, which could prolong the procedure. At the time of writing, the most appropriate means of taking the issue forward was still under discussion.

### European Food Safety Authority (EFSA)

6. The following Opinions have been published by the EFSA Scientific Panels FEEDAP and CONTAM since the Committee was updated in March 2009:

Additive / contaminant	Additive group / contaminant description	EFSA Opinion
Endo-1,4- $\beta$ -xylanase produced by <i>Trichoderma reesei</i> RF5427	Zootechnical (digestibility enhancer)	Enzyme produced by transgenic <i>T. reesei</i> . Positive Opinion: no recombinant DNA detected in the product. Efficacy and safety examined in a previous opinion.
<i>Lactobacillus acidophilus</i> NBIMCC 8242, <i>Lactobacillus helveticus</i> NBIMCC 8269, <i>Lactobacillus bulgaricus</i> NBIMCC 8244, <i>Lactobacillus lactis</i> NBIMCC 8250, <i>Streptococcus thermophilus</i> NBIMCC 8253 and <i>Enterococcus faecium</i> NBIMCC 8270	Zootechnical (gut flora stabiliser)	Unable to conclude on safety and efficacy in chickens for fattening and pigs for fattening.
<i>Bacillus cereus var. toyoi</i> NCIMB 40112	Zootechnical (gut flora stabiliser)	Positive Opinion for use in rabbit breeding does.
<i>Clostridium butyricum</i> MIYAIRI 588	Zootechnical (gut flora stabiliser)	Positive Opinion for use in chickens for fattening.
<i>Enterococcus faecium</i> DSM 7134	Zootechnical (gut flora stabiliser)	Unable to conclude on safety and efficacy in chickens for fattening.
<i>Escherichia coli</i> LMG S-17146	Zootechnical (gut flora stabiliser)	Positive Opinion for use horses above 1 year of age. Unable to conclude on safety for horses below 1 year.
<i>Saccharomyces cerevisiae</i> MUCL 39885	Zootechnical (other zootechnical additive)	Positive Opinion for use in sows.
<i>Saccharomyces cerevisiae</i> CBS 493.94	Zootechnical (digestibility enhancer / gut flora stabiliser)	Positive Opinion for extension of authorisation to the whole life of horses. Unable to support a reduction to the

Additive / contaminant	Additive group / contaminant description	EFSA Opinion
		minimum dose.
<i>Saccharomyces cerevisiae</i> CNCM I-1077	Zootechnical (other zootechnical additive)	Positive Opinion: efficacy demonstrated in adult leisure horses. Safety examined in a previous Opinion.
<i>Pediococcus acidilactici</i> CNCM MA 18/5 M	Zootechnical (other zootechnical additive)	Positive Opinion for use in salmonids. Unable to conclude on efficacy in non-salmonid fish.
<i>Pediococcus acidilactici</i> CNCM MA 18/5 M	Zootechnical (other zootechnical additive)	Safety confirmed, but unable to conclude on efficacy in shrimp as cannot extrapolate results to European farming conditions.
Guanidinoacetic acid	Nutritional (?)	Safety confirmed for consumers, users and the environment, but safety in target animals only confirmed at lowest proposed dose. Recommended amendment to category and functional group as not an essential nutrient.
Selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399	Nutritional (compounds of trace elements)	Positive Opinion for the use in all species.
Zinc chelate of hydroxy analogue of methionine	Nutritional (compounds of trace elements)	Positive Opinion for use in chickens for fattening. Conclusion could not be extended to other poultry categories or to other species.
25-hydroxycholecalciferol	Nutritional (vitamin)	Positive Opinion for safety and efficacy in all poultry species and pig categories.
Ractopamine	A phenethanolamine $\beta$ -adrenoceptor agonist	The substance is authorised for use in many non-EU countries; $\beta$ -agonists are prohibited for use as growth promoters in food producing animals in the EU. EFSA were asked to produce an Opinion on the JECFA evaluation and see if it was possible to set MRLs. EFSA concluded that there was not enough data to derive an ADI and no proposal for maximum residue levels could be made.
Saponins in <i>Madhuca longifolia</i>	Undesirable substance found in many plants (including <i>Madhuca</i> )	Possible use as feed for livestock, but not imported into the EU. Human exposure from consumption of animal products is unlikely; only potential source would be imported foods of animal origin. Consumer exposure to <i>Madhuca</i> saponins in the EU negligible.
Nitrite	Undesirable substance naturally present in animal feed; formed	Adverse effects from excessive exposure seen in pigs and ruminants. Based on estimated intake for pigs and cattle,

Additive / contaminant	Additive group / contaminant description	EFSA Opinion
	by nitrogen cycle and converted to nitrate, a major nutrient for plants.	current maximum permitted levels do not pose concerns for animal health. No concerns for human health.

**Standing Committee on the Food Chain and Animal Health (SCoFCAH):  
Animal Nutrition Section**

Notes

7. Votes in favour were obtained for the authorisation of nine feed additives at the February, March and April 2009 meetings of SCoFCAH. These are summarised below.

Additive	Additive type	Vote in favour achieved for
Endo-1,4- $\beta$ -xylanase EC (3.2.1.8) produced by <i>Bacillus Subtilis</i> (LMG S-15136)	Zootechnical (enzyme)	Permanent authorisation for laying hens under Directive 70/524/EEC.
Endo-1,4- $\beta$ -xylanase (EC 3.2.1.8) produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135)	Zootechnical (enzyme)	Permanent authorisation for weaned piglets and laying hens under Directive 70/524/EEC.
Endo-1,3(4)- $\beta$ -glucanase (EC 3.2.1.6) and endo-1,4- $\beta$ -xylanase (EC 3.2.1.8) produced from <i>Penicillium funiculosum</i> (IMI SD101)	Zootechnical (enzyme)	Permanent authorisation for weaned piglets and ducks under Directive 70/524/EEC.
Endo-1,4- $\beta$ -xylanase EC 3.2.1.8 and endo-1,4- $\beta$ -glucanase EC 3.2.1.4 produced by <i>Aspergillus niger</i> DSM 18404	Zootechnical (digestibility enhancer)	Permanent authorisation for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks.
6-phytase EC 3.1.3.26 produced by <i>Aspergillus oryzae</i> (DSM 17594)	Zootechnical (digestibility enhancer)	Authorised as a feed additive for chickens for fattening.
<i>Bacillus cereus var. toyoi</i> NCIMB 40112	Zootechnical (gut flora stabiliser)	Permanent authorisation for rabbit breeding does
L-valine produced from <i>E.coli</i> K12 AG314	Nutritional (amino acid)	Reformulation of existing product. Authorised as an amino acid for all species.
6-phytase EC 3.1.3.26 produced by	Zootechnical (digestibility enhancer)	Reformulation of existing product. Authorised for chickens for fattening,

<b>Additive</b>	<b>Additive type</b>	<b>Vote in favour achieved for</b>
<i>Schizosaccharomyces pombe</i> ATCC 5233		turkeys for fattening, laying hens, ducks for fattening, weaned piglets, pigs for fattening and sows.
<i>Saccharomyces cerevisiae</i> MULC 39885	Zootechnical (gut flora stabiliser)	Authorised as a feed additive for sows.
<i>Saccharomyces cerevisiae</i> NCYC Sc 47	Zootechnical (gut flora stabiliser)	Administrative amendment to terms of authorisation (change of trade name of product).

### Mycotoxin binders

8. A vote in favour was achieved for a Commission proposal regarding the establishment of a new functional group of feed additives (substances for reduction of the contamination of feed by mycotoxins) under Annex I of Regulation 1831/2003 on additives for use in animal nutrition. EFSA has been asked to provide an Opinion regarding guidelines for the preparation and presentation of feed additive applications in this new functional group. This will probably require an amendment of the annexes of Regulation 429/2008 on guidelines for the preparation and presentation of feed additive applications.

### Undesirable substances

9. A vote in favour was achieved for a number of amendments to the Undesirable Substances Directive 2002/32. The amendments are summarised in the table below.

<b>Undesirable substance</b>	<b>Products intended for animal feed</b>	<b>Previous Maximum Permitted Level in mg/kg</b>	<b>New Maximum Permitted Level in mg/kg</b>
Arsenic <sup>a</sup>	Feedingstuffs obtained from the processing of fish or other marine animals, including fish	15 <sup>b</sup>	25 <sup>b</sup>
	Iron particles used as tracer	-	50
	Additives belonging to the functional group of compounds of trace elements except:	-	30
	- copper sulphate pentahydrate and copper carbonate - zinc oxide, manganese oxide and copper oxide	-	50 100

Undesirable substance	Products intended for animal feed	Previous Maximum Permitted Level in mg/kg	New Maximum Permitted Level in mg/kg
	Complete feedingstuffs with the exception of: - complete feedingstuffs for fish and complete feedingstuffs for fur animals	2 6 <sup>b</sup>	2 10 <sup>b</sup>
Theobromine	Complete feedingstuffs with the exception of: - complete feedingstuffs for adult cattle - complete feedingstuffs for pigs - complete feedingstuffs for dogs, rabbits, horses and fur animals	300 700 300 300	300 300 200 50
Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination, including:  <del><i>Datura sp. stramonium L.</i></del>	All feedingstuffs	3000  1000	3000  1000
<del>Castor oil plant — <i>Ricinus communis L.</i></del>  Seeds and husks from <i>Ricinus communis L.</i> , <i>Croton tiglium L.</i> and <i>Abrus precatorius L.</i> as well as their processed derivatives, separately or in combination	All feedingstuffs	10 (expressed in castor oil husks)	10

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<sup>a</sup> Maximum levels refer to total arsenic

<sup>b</sup> Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 ppm. This analysis is of particular importance for the seaweed species *Hizikia fusiforme*

#### CRL fees for feed additives

10. A vote in favour was achieved for the Commission proposal to change the fee system for applications of authorisation of feed additives under

Regulation 378/2005 on the duties and tasks of the Community Reference Laboratory (CRL). The fee reduction is limited to applications concerning chemically defined flavourings (a category covering more than two thirds of the entries in the Community Register of authorised feed additives) that are grouped and contain similar methods of analysis particularly of the type multi-analyte methods, but there is the possibility of widening the fee reduction to other functional groups in the future. The fee reduction offers the industry significant savings for certain feed additive reauthorisations under Article 10 of Regulation 1831/2003 in 2010.

### Grey area products

11. The Commission introduced an initiative to clarify the categorisation of products as feed materials or feed additives. Member States have been asked to provide examples of products where the categorisation was unclear (so called ‘grey area products’) and how categorisation should be defined. Discussions currently focus on the status of specific products rather than an overall principle for categorisation.

### Proposed changes to limits for certain contaminants in animal feed

12. Following the EFSA Opinions on mercury and gossypol as undesirable substances in animal feed, the Commission is to propose further amendments to the Undesirable Substances Directive 2002/32. These are summarised in the table below. The Commission signalled that a vote would take place on these amendments at the June 2009 SCOFAH meeting.

<b>Undesirable substance</b>	<b>Products intended for animal feed</b>	<b>Previous Maximum Permitted Level in mg/kg</b>	<b>New Maximum Permitted Level in mg/kg</b>
Mercury	Feed materials with the exception of	0.1	0.1
	- feedingstuffs produced by the processing of fish or other marine animals	0.3	0.5
	Compound feed with the exception of:	0.1	0.1
	- compound feed for fish - compound feed for dogs, <b>cats and mink</b>	0.2 0.3	0.1 0.4
Gossypol	Complete feedingstuffs with the exception of:	20	20
	-complete feedingstuffs for adult cattle, <del>sheep and goats</del>	500	500
	- complete feedingstuffs for poultry	100	100



Undesirable substance	Products intended for animal feed	Previous Maximum Permitted Level in mg/kg	New Maximum Permitted Level in mg/kg
	(except laying hens), <b>goats</b> , calves <b>and kids</b> -complete feedingstuffs for rabbits, <b>sheep (except lambs)</b> and pigs (except piglets)	60	60

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Additions shown in **bold**

13. The Commission is also considering proposals for simplifications to the current controls for nitrite in feed and will delete of the current control on *Madhuca longifolia* in line with recommendations from EFSA.

### Incidents

#### **Marigold dioxins contamination**

14. The FSA received a Rapid Alert System for Food and Feed (RASFF) notification from the Belgian authorities regarding excessive levels of dioxins and dioxin-like PCBs in ground dried flowers of *Tagetes erecta* (marigolds) from India on 17 February 2009, alerting the Agency of distribution to the UK. The product had been used in premixtures intended for organic poultry feed with the intention to add colour to food of animal origin. The FSA carried out a risk assessment based on known and assessed rates of incorporation of the additive into finished feed; it was calculated that the actual risk to animal health (and thus consumers) would be very low. A recall of feed was not requested, but the Agency advised companies to not use unused stocks of the additive and/or premixtures incorporating the additive.

**ACAF Secretariat  
May 2009**